UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

GERALD LENDEL, 06-CV-6651

Plaintiff, DECISION and ORDER

vs.

TOMMY THOMPSON, SECRETARY of the DEPARTMENT of HEALTH and HUMAN SERVICES,

Defendant.

INTRODUCTION

Plaintiff, Gerald Lendel ("Lendel") commenced an action against the United States Secretary of Health and Human Services alleging that the Secretary erred in denying Medicare coverage for air ambulance service provided on October 21, 1997 from Buffalo, New York to Washington Adventist Hospital in Tacoma Park, Maryland. Lendel asserted that the Secretary erred because the transport was reasonably necessary. The Secretary argued that coverage was not available because the service was not reasonable and necessary since the procedure for which he was being transported was admittedly investigational and experimental in nature. The decision of the Administrative Law Judge ("ALJ")dated May 5, 2000 denied plaintiff's claim. This decision became final on October 21, 2002 when the Departmental Appeals Board denied plaintiff's request for review, following which plaintiff commenced

this action on December 27, 2002.[1] On July 15, 2003, defendant filed a motion for judgment on the pleadings. On September 30, 2003, plaintiff cross-moved for judgment on the pleadings. For the reasons that follow, I find that there is substantial evidence to support the Secretary's conclusion that the transportation was not reasonable and necessary. Accordingly, plaintiff's motion for summary judgment is denied and defendant's motion for summary judgment is granted.

DISCUSSION

Plaintiff contends that he has met the conditions necessary for Medicare coverage of air transportation to the hospital in Maryland for an experimental procedure. Medicare Part B covers ambulance services when "(t)he use of other means of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations." 42 U.S.C. § 1395(s)(7). The Medicare statute authorizes the Secretary to specify "in regulations" additional criteria for determining coverage of ambulance services. The Secretary has promulgated such regulations. 42 C.F.R. §§ 410.40 and 410.41. These regulations provide that "(t)he beneficiary's condition must require both the ambulance transportation itself and the level of service provided

[1] This case (formerly civil case 02-CV-931E(Sr)) was transferred to the undersigned by the Honorable Richard J. Arcara, Chief Judge, United States District Court, Western District of New York by Order dated December 27, 2006.

in order for the billed service to be considered medically necessary." 42 C.F.R. § 410.40(d)(1). Further, Medicare only grants coverage "(f)rom any point of origin to the nearest hospital . . . that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital . . .must have available the type of physician or physician specialist needed to treat the beneficiary's condition." 42 C.F.R. § 410.40(e)(1).

Plaintiff presents uncontradicted evidence that his condition required both the ambulance transport and the level of service associated with such transportation. He was suffering from a serious heart condition and had endured two coronary artery bypass surgeries. He was hospitalized with angina attacks occurring three to four times each day and was on oxygen continuously. Plaintiff was accepted for a research protocol at Washington Adventist Hospital after his own doctors concluded that surgical intervention was not feasible and that his only option with traditional care was medical management. It is undisputed that the treatment received by plaintiff, Percutaneous Transmyocardial Laser Punctures ("PTLP") was experimental and not covered by Medicare. The location in Maryland was the closest facility capable of furnishing this experimental treatment. Further, the parties agree that the only reason for the air transportation at issue was for plaintiff to undergo the experimental treatment.

The ALJ concluded that "[insofar] as the beneficiary was being transported in order to undergo a non-covered procedure, Medicare regulations and policy direct that dependent services, such as air ambulance transportation, are not medically necessary." (Tr. 36)

STANDARD OF REVIEW

Review of an ALJ decision is limited to determining whether there is substantial evidence in the record to support the Secretary's decision. Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401, 91 S.Ct. 1420, 28 L.Ed.2d 842 (1971), *quoting*, Consolidated Edison Co. v. N.L.R.B., 305 U.S. 197, 229 59 S.Ct. 206, 83 L.Ed. 126 (1938).

Substantial evidence exists in the record which supports the conclusion of the ALJ that the ambulance service is not a covered expense under Medicare. The Secretary has the authority to determine which items or services are covered under Medicare Part B. 42 U.S.C. §1395ff(a). The Secretary uses regulations, the Federal Register and manuals to direct carriers as to which items or services will be paid under Medicare. Furlong v. Shalala, 238 F.3d 227, 229 (2d Cir. 2001). These regulations, manuals and Federal Register notices are binding upon the Medicare carriers. The Secretary's regulations are "entitled to controlling weight unless they are 'arbitrary, capricious, or manifestly contrary to

the statute . . .'" Abiona v. Thompson, 237 F.Supp. 2d 258, 265 (E.D.N.Y. 2002). Further, agency manual provisions are "given substantial deference unless another reading is compelled by the regulation's plain language." Id. at 265-266.

The Medicare Act and its regulations are clear that no payment may be made under either Part A or Part B of the Medicare Act for any item or service that is not ". . . reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. §1395y(a)(1)(A). Items and services that are experimental in nature are not considered to be reasonable and/or necessary for purposes of the Medicare Act and therefore are not covered. Goodman v. Sullivan, 891 F.2d 49, 450 (2d Cir. 1989). Medicare policy as stated in Medicare Carrier's Manual §2300.1 states that the Medical and hospital services that are related to non-covered services are not covered under the Medicare Act.

Lendel contends that this Court cannot consider the manual language because it is not the basis of the underlying ALJ decision. He characterizes the Commissioner's characterization "post-hoc rationalization" which is prohibited. Moreover, he contends that pursuant to Social Security policy as stated in the manual, services that are traditionally "uncovered" services can be, and are to be covered by Medicare if the patient received services that are covered by medicade during the same hospital

stay. Finally, he argues that the manual cannot override what he considers to be the plain language of the statute, and cannot usurp a Presidential mandate to increase Medicare enrollees' participation in clinical trials.

This Court does not find plaintiff's arguments persuasive. The Medicare Carrier's Manual clearly states that the "[s]ervices 'related to' noncovered services . . . are not covered services under Medicare." Medicare Carrier's Manual § 2300.1. This policy should be "given substantial deference unless another reading is compelled by the regulation's plain language." Abiona, 237 F.Supp.2d at 265-66. The language of the manual is consistent with the Medicare regulation that it interprets which prohibits Medicare coverage for any item or service that is not reasonable and necessary for the diagnosis or treatment of illness or injury. The medical procedure at issue in this case, "PTLP", is considered experimental or not "reasonable or necessary" and, therefore, the transportation to such service is not reasonable or necessary under the regulations. The Executive Memorandum upon which plaintiff relies to assert that a Presidential mandate requires coverage of related services to experimental procedures does not override established Medicare policy. The memorandum is not an executive order and does not create any right of action or authority to create any enforceable right or benefit. Feldman v. Reno, 2000 WL 4158, 4 (S.D.N.Y. 2000).

Finally, the rationale to deny coverage is not "post-hoc". The ALJ clearly stated the basis for his decision denying Medicare payment was because Medicare regulations and policy direct that transportation to a non-covered procedure is not medically necessary. (Tr. 36)

CONCLUSION

I find that there is substantial evidence in the record to support the ALJ's conclusion that plaintiff is not entitled to Medicare coverage for air transportation. Accordingly, the decision of the Commissioner denying plaintiff's disability claim is affirmed, the plaintiff's motion for summary judgment is denied, the defendant's motion for judgment on the pleadings is granted and the complaint is dismissed

ALL OF THE ABOVE IS SO ORDERED.

S/Michael A. Telesca

MICHAEL A. TELESCA
United States District Judge

DATED: Rochester, New York
March 6, 2007